Proposals to Minimize Disruption on FDA's Premarket Device Review Program

"(a) Notwithstanding a lapse in appropriations for the Food and Drug Administration, the Secretary shall accept device submissions described in section 738(a)(2) of the Food, Drug, and Cosmetic Act and registrations described in section 738(a)(3) of such Act during such lapse in appropriations if an applicable fee has been submitted for such submission or registration, and such fee shall be considered to have been paid and is hereby appropriated and shall remain available until expended."

"(b)(1) During any time period in which there is a lapse in government appropriations for the Food and Drug Administration, the Secretary shall apply to the process for the review of device applications any fees paid for device submissions described in section 738(a)(2) of the Food, Drug, and Cosmetic Act and registrations described in section 738(a)(3) of such Act, and either a submission has not been received for such submission fee or a remitter has not been identified for such establishment fee, and such fees are hereby appropriated and shall remain available until expended.

"(2) Notwithstanding the application of a user fee for the process for the review of device applications pursuant to paragraph (1), such fee shall be deemed to have been paid for purposes of section 738(f)(1) of the Food, Drug, and Cosmetic Act if the Secretary subsequently receives a submission or registration for such fee."